4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0286]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry: Formal Meetings between the Food and Drug Administration and Biosimilar Biological Product Sponsors or Applicants

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0802. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry: Formal Meetings between the Food and Drug Administration and Biosimilar Biological Product Sponsors or Applicants

OMB Control No. 0910-0802--Extension

This information collection supports the above captioned Agency guidance. The Biologics Price Competition and Innovation Act of 2009, the Biosimilar User Fee Act of 2012, and the recent passage of the Biosimilar User Fee Amendments of 2017 (BsUFA II) under Title IV of the FDA Reauthorization Act of 2017, authorize user fees for biosimilar biological products. FDA has committed to meeting certain performance goals in connection with the reauthorized biosimilar user fee program. To provide recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of biosimilar biological products regulated by the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) and assist sponsors and applicants in generating and submitting meeting requests and the associated meeting packages to FDA for biosimilar biological products, we developed guidance for industry entitled "Formal Meetings Between FDA and Biosimilar Biological Products Sponsors or Applicants." The guidance describes our current thinking on how we intend to interpret and apply certain provisions of BsUFA II and provides information on specific performance goals for the management of meetings associated with the development and review of biosimilar biological products. The guidance document includes two types of information collection: (1) the submission of a meeting request containing certain information and (2) the submission of the information package(s) that accompany the meeting request.

A. Request for a meeting

Under the guidance, a sponsor or applicant interested in meeting with CDER or CBER should submit a meeting request to the sponsor's or applicant's application (i.e., investigational new drug application, biologics license application). If there is no application, a sponsor or applicant should submit the request to either the appropriate CDER division director, with a copy sent to the division's chief of project management staff, or to the division director of the appropriate product office within CBER, but only after first contacting the appropriate review division or the Biosimilars Program staff, CDER, Office of New Drugs to determine to whom the request should be directed, how it should be submitted, and the appropriate format for the request and to arrange for confirmation of receipt of the request. Under the guidance, FDA requests that sponsors and applicants incorporate certain information in the meeting request, including:

1. product name,

2. application number (if applicable),

proposed proper name or proper name (post licensure),

4. structure,

5. reference product name,

6. proposed indication(s) or context of product development,

7. meeting type being requested (the rationale for requesting the meeting type should be included),

8. a brief statement of the purpose of the meeting, including a brief background of the issues underlying the agenda. It can also include a brief summary of completed or planned studies and clinical trials or data the sponsor or applicant intends to discuss at the meeting, the

general nature of the critical questions to be asked, and where the meeting fits in the overall development plans.

9. a list of specific objectives/outcomes expected from the meeting,

10. a proposed agenda, including times required for each agenda item,

11. a list of questions grouped by discipline and a brief explanation of the context and purpose of each question,

12. a list of all individuals with their titles and affiliations who will attend the requested meeting from the requestor's organization and consultants,

13. a list of FDA staff, if known, or disciplines asked to participate in the requested meeting,

14. suggested dates and times for the meeting, and

15. the proposed format of the meeting (i.e., face to face meeting, teleconference, or videoconference).

This information will be used by FDA to determine the utility of the meeting, to identify FDA staff necessary to discuss proposed agenda items, and to schedule the meeting.

B. Information Package

FDA requests that a sponsor or applicant submit a meeting package to the appropriate review division with the meeting request. FDA recommends that the information packages generally include:

1. product name and application number (if applicable),
2. proposed proper name or proper name (post licensure),
3. structure,
4. reference product name,

5. proposed indication(s) or context of product development,
6. dosage form, route of administration, dosing regimen (frequency and duration), and presentation(s),
7. a list of all sponsor's or applicant's attendees and consultants with their titles and affiliations who will attend the requested meeting,
8. background that includes a brief history of the development program and the status of product development (e.g., chemistry, manufacturing, and controls; nonclinical; and clinical, including any development outside the United States, as applicable),
9. a brief statement summarizing the purpose of the meeting,
10. the proposed agenda,
11. a list of questions for discussion grouped by discipline and with a brief summary for each question to explain the need or context for the question, and
12. data to support discussion organized by discipline and question.

The purpose of the meeting package is to provide FDA staff the opportunity to adequately prepare for the meeting, including the review of relevant data concerning the product.

Description of Respondents: A sponsor or applicant for a biosimilar biological product who requests a formal meeting with FDA regarding the development and review of a biosimilar biological product.

In the *Federal Register* of June 18, 2018 (83 FR 28234), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

GFI: Formal Meetings between FDA and Biosimilar Biological Product Sponsors or Applicants	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
CDER Meeting Requests	36	2.5	89	15	1,335
CBER Meeting Requests	2	1	2	15	30
CDER Information Packages	29	2.2	64	30	1,920
CBER Information Packages	2	2	4	30	120
TOTAL					3,405

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Since last OMB approval, there has been an increase in meeting requests with CDER and a corresponding increase in the number of information packages. Accordingly, we have adjusted our estimate upward by six respondents to CDER meeting requests. We attribute this change to an increase in biosimilar product development.

Dated: September 4, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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